REMARKS

Please amend claims 1, 25, 44, and 60 as indicated in the listing of claims. Claims 1-4, 16, 19, 25, 28, 29, 31-37, 39-42, 44, 48-52, 55-57, 59-61, 76, 78-86 are pending and at issue. These amendments and additions add no new matter as the claim language is fully supported by the specification and original claims.

Amendments to the Claims

The Office Action stated that "methods and products which require a primer consisting of instant SEQ ID NO: 3 are free of the prior art." (Office Action, page 2.) Claims 1, 25, 44 and 60 have been amended to include the limitation of a primer consisting of SEQ ID NO: 3. Thus, the recitation in the claims is commensurate in scope with the unexpected property referred to in the Office Action and the fact that primers consisting of SEQ ID NO: 3 and any combination requiring such a primer would be free of the art.

Rejections under 35 U.S.C. §112, Second Paragraph

Claims 1, 2, 3, 4, 16, 18, 19, 79 and 80 were rejected for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse these rejections as they apply to the amended claims for the reasons below.

According to the Office Action, the claims are "confusing because the claim limitations conflict with each other." The Office Action alleges that the "claim requires that primers hybridize to 'a sequence flanking and within fifty nucleotides of' one of the gene sequences" and "the claim also requires that one of the primers include SEQ ID NO: 3" which occurs "within nucleotides 2043-4290, NOT flanking it." (Office Action, page 3.) Without acquiescing to the reasoning of the Office Action, Applicants have amended independent claim 1 to recite that the nucleotide sequence is within one of the polysystic kidney disease-associated protein-1 gene sequences. Accordingly, withdrawal of the rejection is respectfully requested.

Claim 18 was rejected as being incomplete for being dependent from cancelled claim 17. As claim 18 was previously withdrawn as being directed to non-elected subject matter (See Office Action dated January 29, 2004, page 2). In a telephone call to the Examiner on October 28, 2008, the Examiner stated that the rejection was in error.

Rejections under 35 U.S.C. §112, First Paragraph

Claims 25, 28-37, 39-42, 44, 48-52, 55-61, 76, 78, and 81-86 were rejected for allegedly failing to comply with the enablement requirement. Applicants respectfully traverse these rejections as they apply to the amended claims for the reasons below.

The Office Action alleges, in pertinent part, that "the claims encompass the identification of a mutation at any position within the amplified products" and that "of all the possible mutations that might be identified within the regions amplified in the rejected method claims, it is highly unpredictable which ones will be associated with disease. Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution toward allowance, independent claims 25, 44 and 60 have been amended to include the limitation "wherein the mutation is located at nucleotides 3110, 3336, 3707, 4168, 6078, 6089, 6326, 7205-7211, 7415, 7433, 7535-7536, 7883, 8159-8160, 8298, 9164, 9213, 9326 of SEQ ID NO:1." Support for the amendments can be found in the Specification as filed. For example, Example 2 in the Specification describes pathogenic mutations or mutations that segregate with a PKD1-associated disorder or ADPKD.

Therefore, the Applicants respectfully submit that the specification properly enables amended claims 25, 28-37, 39-42, 44, 48-52, 55-61, 76, 78, and 81-86. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. §112, First Paragraph

Claims 25, 28-37, 39-42, 44, 48-52, 55-61, 76, 78 and 81-86 were rejected for allegedly failing to comply with the written description requirement. Applicants respectfully traverse these rejections as they apply to the amended claims for the reasons below.

The Office Action alleges that the "claims set forth identifying the presence or absence of a mutation in an amplification product that is indicative of or diagnostic of a PKD1-associated disorder or of ADPKD in particular" and "the claims do not include the detection of any of these possible mutations, only the ones that are 'indicative' of a disorder or wherein the presence of the mutation identifies the subject is at risk or not at risk for ADPKD." (Office Action, page 7.)

Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution toward allowance, independent claims 25, 44 and 60 have been amended to include the limitation "wherein the mutation is located at nucleotides 3110, 3336, 3707, 4168, 6078, 6089, 6326, 7205-7211, 7415, 7433, 7535-7536, 7883, 8159-8160, 8298, 9164, 9213, 9326 of SEQ ID NO:1." Support for the amendments can be found in the Specification as filed. For example, Example 2 in the Specification describes pathogenic mutations or mutations that segregate with a PKD1-associated disorder or ADPKD.

In view of the above amendments, withdrawal of rejection of claims 25, 28-37, 39-42, 44, 48-52, 55-61, and 76-78 under 35 U.S.C. §112, first paragraph is respectfully requested.

Conclusion

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

No fee is deemed necessary with the filing of this paper. However if any fees are due, the Commissioner is hereby authorized to charge any fees, or make any credits, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,

Date: November 26, 2008

Antony Novom, J.D.
Registration No. 45,517 for
Lisa A. Haile, J.D., Ph.D.
Registration No. 38,347
Telephone: (858) 677-1456
Facsimile: (858) 677-1465

DLA PIPER LLP (US)
4365 Executive Drive, Suite 1100
San Diego, CA 92121-2133
USPTO Customer No. 28213